We Claim:

1. A stable oral composition of azithromycin comprising:

an azithromycin premix comprising azithromycin monohydrate and at least one additive;

at least one pharmaceutically accepted excipient; and

optionally, at least one taste masking agent.

2. The composition of claim 1 wherein the additive comprises one or more of at least one binder, at least one disintegrant, at least one hydrophobic material, at least one surfactant, at least one lubricant, at least one diluent, and at least one taste masking agent.

3. The composition of claim 2 wherein the binder comprises one or more of acacia, methylcellulose, carboxymethylcellulose, hydroxypropyl methylcellulose, hydroxypropylcellulose, polyvinylpyrrolidone, pregelatinized starch, gum tragacanth and sodium alginate.

4. The composition of claim 2 wherein the disintegrant comprises one or more of pregelatinized starch, sodium starch glycolate, sodium carboxymethylcellulose, crosslinked sodium carboxymethylcellulose, microcrystalline cellulose, low substituted hydroxypropyl cellulose and cross-linked polyvinylpyrrolidone.

5. The composition of claim 2 wherein the hydrophobic material comprises corn oil.

6. The composition of claim 2 wherein the surfactant comprises one or more of polysorbates, castor oil and derivatives, and sodium lauryl sulphate.

7. The composition of claim 2 wherein the lubricant comprises one or more of magnesium stearate, stearic acid, glyceryl behenate, polyethylene glycol, ethylene oxide polymers, sodium lauryl sulfate, magnesium lauryl sulfate, sodium oleate, sodium stearyl fumarate, talc, and colloidal silicon dioxide.

8. The composition of claim 2 wherein the diluent comprises one or more of lactose, sucrose, dextrose, mannitol, sorbitol, starch, microcrystalline cellulose, and dibasic calcium phosphate.

9. The composition of claim 1 wherein the taste masking agent comprises one or more of magnesium hydroxide, magnesium carbonate, sodium carbonate, sodium

phosphate, sodium citrate, calcium gluconate, meglumine, sodium chloride, sodium phosphate dibasic heptahydrate, sodium phosphate dibasic dihydrate, and anhydrous dibasic calcium phosphate.

10. The composition of claim 1 wherein the pharmaceutically accepted excipient comprises one or more of at least one binder, at least one viscosity increasing agent, at least one disintegrant, at least one surfactant, at least one diluent, at least one lubricant, at least one dispersing agent, at least one flavoring agent, and at least one sweetening agent.

11. The composition of claim 10 wherein the viscosity-increasing agent comprises one or more of xanthan gum, guar gum, locust bean gum, gum tragacanth, alginates, sodium carboxymethylcellulose, polyvinylpyrrolidone, hydroxypropylcellulose, and hydroxypropyl methylcellulose.

12. The composition of claim 10 wherein the flavoring agent comprises one or more of menthol, flavour peppermint, flavour cherry, flavour banana, and flavour fruit gum.

13. The composition of claim 10 wherein the sweetening agent comprises one or more of aspartame, saccharin sodium, sucralose, and acesulfam K.

14. The composition of claim 10 wherein the dispersing agent comprises one or more of colloidal silicon dioxide and talc.

15. The composition of claim 1 wherein the composition is prepared by a dry granulation method.

16. The composition of claim 1 wherein the composition comprises one or more of a tablet, a capsule, a powder for oral suspension, and a unit dose packet.

17. The composition of claim 1 wherein the composition shows an absence of azithromycin dihydrate after storage at room temperature and humidity conditions for a period of at least two months, as determined by using X ray diffraction.

18. The composition of claim 1 wherein the composition has at least 90% dissolution of azithromycin within 30 minutes when an amount of the composition equivalent to 200mg of azithromycin is tested according to USP-2 dissolution apparatus using 900ml sodium phosphate buffer pH 6.0, 37°C, and paddle speed of 100 rpm.

19. A process for making a stable oral composition of azithromycin, the process comprising:

combining azithromycin monohydrate with at least one additive to form an azithromycin premix;

combining at least one pharmaceutically accepted excipient with the azithromycin premix; and

optionally, adding at least one taste masking agent.

20. The process of claim 19 wherein the additive comprises one or more of at least one binder, at least one disintegrant, at least one hydrophobic material, at least one surfactant, at least one lubricant, at least one diluent, and at least one taste masking agent.

21. The process of claim 20 wherein the binder comprises one or more of acacia, methylcellulose, carboxymethylcellulose, hydroxypropyl methylcellulose, hydroxypropylcellulose, polyvinylpyrrolidone, pregelatinized starch, gum tragacanth and sodium alginate.

22. The process of claim 20 wherein the disintegrant comprises one or more of pregelatinized starch, sodium starch glycolate, sodium carboxymethylcellulose, crosslinked sodium carboxymethylcellulose, microcrystalline cellulose, low substituted hydroxypropyl cellulose and cross-linked polyvinylpyrrolidone.

23. The process of claim 20 wherein the hydrophobic material comprises corn oil.

24. The process of claim 20 wherein the surfactant comprises one or more of polysorbates, castor oil and derivatives, and sodium lauryl sulphate.

25. The process of claim 20 wherein the lubricant comprises one or more of magnesium stearate, stearic acid, glyceryl behenate, polyethylene glycol, ethylene oxide polymers, sodium lauryl sulfate, magnesium lauryl sulfate, sodium oleate, sodium stearyl fumarate, talc, and colloidal silicon dioxide.

26. The process of claim 20 wherein the diluent comprises one or more of lactose, sucrose, dextrose, mannitol, sorbitol, starch, microcrystalline cellulose, and dibasic calcium phosphate.

27. The process of claim 20 wherein the taste masking agent comprises one or more of magnesium hydroxide, magnesium carbonate, sodium carbonate, sodium phosphate, sodium citrate, calcium gluconate, meglumine, sodium chloride, sodium phosphate dibasic heptahydrate, sodium phosphate dibasic dihydrate, and anhydrous dibasic calcium phosphate.

28. The process of claim 19 wherein forming the azithromycin premix comprises mixing the azithromycin monohydrate and additive.

29. The process of claim 28 wherein forming the azithromycin premix further comprises compacting.

30. The process of claim 28 wherein forming the azithromycin premix further comprises granulating.

31. The process of claim 19 wherein the composition has at least 90% dissolution of azithromycin within 30 minutes when an amount of the composition equivalent to 200mg of azithromycin is tested according to USP-2 dissolution apparatus using 900ml sodium phosphate buffer pH 6.0, 37°C, and paddle speed of 100 rpm.

32. The process of claim 19 wherein the composition shows an absence of azithromycin dihydrate after storage at room temperature and humidity conditions for a period of at least two months, as determined by using X ray diffraction.

33. A method for treating a microbial infection in a human, the method comprising administering to the human a stable oral composition of azithromycin as claimed in claim 1.